UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANGELA BOWDRIE, et al.,

Plaintiffs,

-against-

SUN PHARMACEUTICAL INDUSTRIES LTD., et al.,

Defendants.

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DECISION AND ORDER

12-CV-853(WFK)(MDG)

Plaintiffs Angela Bowdrie, Sharon Brow, John L. Brown, Leonard Brown, Bonnie Brubaker, Gail Cambell, Ada Cobbs, Michelle Couser, Eva Douglass, Josephine Dyer, Carol Groomes, Latoya Hill, Danielle Hyden, Lonita Jackson, Loretta Johnson, Reginald Kennard, Dorothy Kind, Susie Lekich, Jan Loput, Annie Morrison, Timothy Nelson, Patricia Parsons, Svetlana Polovets, Patricia Rocha, Ashley Smith, Yelonda Swearengin, Monte Tyson, and Dorothy Young (collectively "Plaintiffs") filed this action in New York State Supreme Court, Kings County on or about October 12, 2011 against Defendants Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), Sun Pharma Global, Inc. ("Sun Global"), Taro Pharmaceutical Industries, Ltd. ("Taro Ltd."), and Taro Pharmaceuticals, U.S.A., Inc. ("Taro Inc."). Plaintiffs filed an Amended Complaint on January 20, 2012. On February 21, 2012, Sun Inc. and Caraco removed this action to the Eastern District of New York. *See* Docket Entry 1 (the "Notice of Removal"). Neither Sun Global nor Taro Ltd. has appeared in this action. The remaining

Defendants (collectively "Defendants") now move to dismiss the Amended Complaint pursuant to Rules 8(a) and 12(b) of the Federal Rules of Civil Procedure. Plaintiffs oppose and move to remand this action to New York State Supreme Court.

This Court denies the motion to remand by Plaintiffs, and grants the motion to dismiss by Defendants in its entirety.

BACKGROUND

Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.* (the "FDCA"), to secure the approval of the Food and Drug Administration ("FDA"), a manufacturer of a new drug must file an application demonstrating the drug is safe, effective, and adequately labeled. 21 U.S.C. § 355(b), (d); 21 C.F.R. § 314.1 *et seq.* The Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, (the "Hatch–Waxman Amendments") amended the FDCA to permit generic drug manufacturers to bypass the approval practice by submitting an "abbreviated new drug application" ("ANDA")—an application showing the proposed generic drug to be the same as a reference listed drug ("RLD") that has already gained FDA approval. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94. The generic must be bioequivalent to and have the same labeling as the RLD. 21 U.S.C. § 355(j)(2)(iv), (v); 21 C.F.R. § 314.94(a)(7), (8).

Plaintiffs are all individuals or their decedents who allege they were injured after ingesting generic Phenytoin Sodium ("Phenytoin"), an antiepileptic manufactured by Defendants. Am. Compl., ¶¶ 9–38. Plaintiffs allege the Phenytoin they ingested differed from the RLD—Dilantin—in terms of labeling and bioequivalence. *Id.* at ¶¶ 4, 5, 8, 91–106, 126–50, 159, 177–226. Plaintiffs allege it is recognized widely in the medical community that the side effects of Phenytoin include what are collectively referred to as "severe cutaneous adverse reactions," or SCAR events, which may result in "painful and debilitating tissue injury and loss,

epidermal blistering, necrosis, and sloughing." *Id.* at ¶ 18. Plaintiffs allege the makers of Dilantin enhanced the warnings regarding SCAR events on their labeling and in a medication guide in July 2009. *Id.* at ¶ 128. Plaintiffs allege Defendants failed to update their labeling to mirror Dilantin's July 2009 revision and failed to implement the Dilantin medication guide. *Id.* at ¶¶ 130–49. Plaintiffs allege the makers of Dilantin implemented changes in the manufacturing process for that drug in 2007, after the FDA had granted Defendants' ANDAs for Phenytoin. *Id.* at ¶¶ 91, 95, 100–05. Plaintiffs allege Defendants failed to assure bioequivalence to Dilantin following the changes in Dilantin's manufacturing process. *Id.* Plaintiffs allege they experienced SCAR events as a result of the differences between the Phenytoin they consumed and Dilantin, and plead the following causes of action under New York state law: (1) strict product liability; (2) negligence; (3) fraud; (4) breach of implied warranties; (5) negligence per se; and (6) wrongful death.

ANALYSIS

I. *Wyeth v. Levine* and *Pliva, Inc. v. Mensing*

Two decisions of the United States Supreme Court, *Wyeth v. Levine*, 555 U.S. 555 (2009) and *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) are at the forefront of all recent products liability actions alleging inadequate warnings by drug manufacturers, including this one.

The plaintiff in *Levine* was injured when the intravenous form of Phenergan, an antihistamine used to treat nausea, caused gangrene that ultimately required the amputation of her right forearm. The plaintiff filed a products liability action in Vermont state court, alleging the drug's labeling was defective because, although it warned of the danger of gangrene following intra-arterial injection, it failed to instruct physicians to use the safer of two methods of intra-arterial injection. The trial judge instructed the jury that evidence of Wyeth's

compliance with FDA requirements did not establish the adequacy of the existing warnings, and the jury found Wyeth liable for negligence and Phenergan defective as a result of inadequate warnings. The Vermont Appellate and Supreme Courts affirmed.

The United States Supreme Court granted Wyeth's petition for certiorari to address, *inter alia*, the issue of impossibility preemption. Wyeth argued it would have been impossible to comply with its state law duty to warn without violating the FDCA and FDA regulations. The Supreme Court rejected Wyeth's argument, finding Wyeth could have could have unilaterally strengthened its warnings without prior FDA approval through the "changes being effected" ("CBE") process, 21 C.F.R. § 314.70(c)(6)(iii), which enables certain labeling changes to be implemented simultaneous to submitting the changes to the FDA for review.

Two years later in *Mensing*, the Supreme Court decided two consolidated cases alleging injuries based on manufacturers' failure to provide adequate labeling for generic metoclopramide, used to treat digestive tract problems. The RLD for generic metoclopramide is Reglan, first approved for use by the FDA in 1980. Evidence shows that a percentage of long-term users of metoclopramide develop tardive dyskinesia, a neurological disorder. The plaintiffs in the consolidated cases developed tardive dyskinesia after taking generic metoclopramide as prescribed for several years beginning in 2001 and 2002, respectively. The manufacturer of Reglan implemented FDA-approved labeling containing enhanced warnings for tardive dyskinesia in 2004 and 2009. The plaintiffs alleged the generic manufacturers were liable under state law for inadequate warnings. The Court of Appeals for the Fifth and Eight Circuits each found the plaintiffs' state law claims were not preempted because means of enhancing warnings were available to the generic manufacturers. *Demahy v. Wyeth Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

The Supreme Court reversed. The Supreme Court deferred to the FDA's interpretation of its regulations that, under the Hatch-Waxman Amendments, the labeling of a generic drug must be the same as the labeling of the RLD. *Mensing*, 131 S. Ct. at 2574–76; *see* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.150(b)(10). That "ongoing federal duty of 'sameness'" precluded manufacturers of generic drugs from unilaterally strengthening their labeling. *Mensing*, 131 S. Ct. at 2575–82. Therefore, because the manufacturers could not simultaneously comply with federal and state law, the Supreme Court held plaintiffs' state law claims were preempted.

II. Motion to Remand

Defendants contend Plaintiffs' allegations of: (1) violations by Defendants of federal law; (2) violations by Defendants of the "federal duty of sameness;" and (3) Defendants' failure to assure bioequivalence with the RLD subject this action to "arising under" jurisdiction. Notice of Removal, ¶¶ 3–22. Plaintiffs now move to remand this action to New York State Supreme Court, Kings County. Because this Court possesses jurisdiction, the motion to remand is denied.

28 U.S.C. § 1331 vests the District Court with "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." The question of whether a claim or cause of action arises under federal law looks to the face of a well-pleaded complaint. *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9–10 (1983). In a state law cause of action, federal question jurisdiction is proper only where "it appears that some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state law claims." *Id.* at 13; *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312–14 (2005).

Plaintiffs argue their claims arise under New York state law, and resolving their claims does not require the resolution of a substantial question of federal law. Pls.' Mem. of Law in

Supp. of Mot. to Remand, 2, 5–9. Plaintiffs submit the Amended Complaint implicates federal law primarily in that it anticipates Defendants' affirmative defense of preemption. *Id.* at 3–4; Pls.' Reply Mem. in Supp. of Mot. to Remand, 1–2, 8–10. Citing *Merrell Dow Pharmaceuticals Inc. v. Thomson*, 478 U.S. 804 (1986), Plaintiffs contend their use of the "federal duty of sameness" as a standard in their state law causes of action is not sufficiently substantial to confer federal question jurisdiction.

Defendants argue Plaintiffs' repeated invocation of the "ongoing federal duty of sameness" implicates substantial federal issues irrespective of the fact the duty is pleaded in conjunction with state law causes of action. Defs.' Mem. in Opp'n to Mot. to Remand, 1–2, 8–11. Defendants argue federal jurisdiction is appropriate because resolving Plaintiffs' claims necessarily implicates substantial and disputed federal issues. *Id.* at 11–14.

A question of federal law is a necessary element of Plaintiffs' state law causes of action. Plaintiffs allege Defendants failed to meet their ongoing duty of sameness by failing to utilize the CBE process to update their FDA-approved labeling to mirror updated Dilantin labeling. Therefore, Plaintiffs' claims fall in the small gap between *Levine* and *Mensing*. Indeed, the boundaries of Plaintiffs' claims sounding in the ongoing federal duty of sameness are established by the FDCA and the Hatch-Waxman Amendments. Therefore, while Plaintiffs' causes of action arise under state law, resolving them necessarily raises a federal question. *Grable*, 545 U.S. at 315; *See W. 14th St. Commercial Corp. v. 5 W. 14th Owners Corp.*, 815 F.2d 188, 195–96 (2d Cir. 1987) (holding where the provisions of the Co-op Abuse Relief Act, 15 U.S.C. § 3607, give rise to a cloud on title, "the statute must necessarily be pleaded in a well-pleaded action to remove that cloud").

The federal question in this case is substantial. In *Merrell Dow*, the issue presented to the Court was solely "whether incorporation of a federal standard in a state-law private action, when Congress has intended that there not be a federal private action for violations of that federal standard, makes the action one 'arising under the Constitution, laws or treaties of the United States.'" 478 U.S. at 805 (citing 28 U.S.C. § 1331). The Court found because Congress did not intend to create a private cause of action under the FDCA, importing a standard from that statute is not, by itself, sufficiently substantial to confer federal question jurisdiction. *Merrell Dow*, 478 U.S. at 813–14 (quoting *Franchise Tax Bd.*, 463 U.S. at 20–21). However, the Court did not foreclose the possibility that a state law cause of action utilizing a federal standard could raise a substantial issue of federal law. Rather, the Court recognized the need for "principled, pragmatic distinctions" and "careful judgments about the exercise of federal judicial power in an area of uncertain jurisdiction." 478 U.S. at 814 (citing *Franchise Tax Bd.*, 463 U.S. at 20–21); *see also W. 14th St. Commercial Corp.*, 815 F.2d at 96 ("[A]ssuming that plaintiffs have no private right of action under [the Co-op Abuse Relief Act], we conclude that the federal elements in plaintiffs' state cause of action would still be sufficiently substantial to confer arising under jurisdiction."); *Virgin Islands Hous. Auth. v. Coastal Gen. Constr. Serv. Corp.*, 27 F.3d 911, 917 (3d Cir. 1994) ("The nature of the federal interest at stake is determinative of whether it is sufficiently substantial to displace state law."). In this case, the federal issue involved goes far beyond simply incorporating a federal standard into a state law cause of action. To the extent they invoke the "federal duty of sameness," Plaintiffs' causes of action implicate the labeling requirements for generic drug manufacturers nationwide. The federal question present in this case involves a responsibility that is in the first instance, and primarily, federal: regulation of the manufacture, marketing, and distribution of drugs.

The federal question at issue here is a sufficiently substantial and necessary element of Plaintiffs' state-law claims to confer original jurisdiction upon this Court pursuant to 28 U.S.C. § 1331. Having so found, we now turn to the merits.

III. Motion to Dismiss

Defendants move to dismiss the Amended Complaint. Defendants argue Plaintiffs' claims are preempted by the FDCA. Defendants further argue Plaintiffs have failed to plausibly state a claim pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6). This Court holds Plaintiffs' failure to warn claims are preempted by federal law. Furthermore, accepting all factual allegations as true, this Court holds Plaintiffs have not stated a claim with respect to their allegation that Defendants' Phenytoin was not bioequivalent to Dilantin.

a. Impossibility Preemption

The Supremacy Clause of the United States Constitution establishes federal law as the "supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. State law is preempted "to the extent of any conflict with a federal statute" irrespective of whether such conflict is express or implied. *Crosby v. Nat'l Foreign Trade Council*, 360 U.S. 363, 372 (2000). Impossibility preemption occurs where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1997).

Impossibility preemption, at issue here, formed the basis of the holding of the United States Supreme Court in *Mensing*. The Supreme Court held the plaintiffs' state law failure to warn claims were preempted because, under the FDCA and FDA regulations, generic drug manufacturers could not unilaterally strengthen their warnings through the CBE process or otherwise. *Mensing*, 131 S. Ct. at 2575–82. However, the Supreme Court left open the

possibility generic manufacturers may be able to use the CBE process in certain situations. Specifically, it deferred to the FDA's interpretation that the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii), allows "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instruction." *Mensing*, 131 S. Ct. at 2575.

Plaintiffs allege the manufacturer of Dilantin altered its labeling and issued a medication guide to enhance warnings concerning SCAR events in July 2009 using the CBE process. Am. Compl., ¶¶ 125–29; Pls.' Mem. in Opp'n to Mot. to Dismiss, at 7–8. Plaintiffs argue at that point it became possible for Defendants to also utilize the CBE process to update their own labeling to mirror Dilantin's labeling. Pls.' Mem. in Opp'n to Mot. to Dismiss, at 8, 13–18. Plaintiffs contend "generic drug makers are permitted to conform their product labels to the labeling of their Reference Listed Drug as soon as the RLD modifies its label using any permissible route of revision." *Id.* at 8. Plaintiffs therefore argue their failure to warn claims are not preempted. *Id.* at 13–18.

Plaintiffs attempt to circumvent the broad holding of *Mensing* by arguing Defendants' obligation to update their labeling accrued before the FDA approved the Dilantin labeling that drug's manufacturer unilaterally updated through the CBE process. However, their argument is contrary to *Mensing* itself. The Supreme Court found "[b]efore the [generic manufacturers] could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so." *Mensing*, 131 S. Ct. 2580; *see also id.* at 2580–81 ("To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance . . . that party cannot independently satisfy those state duties for pre-emption purposes."). This Court will not construe "special effort" by the FDA to include

unilateral action by the manufacturer of Dilantin. That either FDA approval of RLD labeling, or a specific FDA directive, is a necessary predicate to generic drug manufacturers' ability to update labeling, including any medication guide, is consistent with the process by which FDA approval of an ANDA is secured in the first instance. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7); *Mensing*, 131 S. Ct. at 2575. Indeed, in deferring to the FDA's interpretation of its regulations, the Supreme Court cited 21 U.S.C. § 355(j)(4)(G) and 21 C.F.R. § 314.94(a)(8), sections which specifically address *initial* approval of generic labeling and require generics to conform to FDA-approved RLD labeling. *Mensing*, 131 S. Ct. at 2575. In short, the preemption exception Plaintiffs seek to create is not supported by the law.

Several district courts have rendered decisions consistent with this Court's conclusion. The courts in *Fisher v. Pelstring,* 817 F. Supp. 2d 791 (D.S.C. 2011) (Wooten, J.) and *Cooper v. Wyeth, Inc.*, No. 09-cv-929, 2012 WL 733846 (M.D. La. Mar. 6, 2012) (Brady, J.) each addressed, *inter alia*, claims that the defendants, manufacturers of generic metoclopramide, did not incorporate FDA-approved warnings used by the RLD, Reglan, into labeling for the drugs plaintiffs alleged caused their injuries. 817 F. Supp. 2d at 804–05; 2012 WL 733846, at *3–4. In each case, the Court found *Mensing's* conflict preemption analysis did not apply to any period during which defendants failed to mirror FDA-approved Reglan labeling. 817 F. Supp. 2d at 805, 818–23; 2012 WL 733846, at *4. In *Coney v. Mylan Pharms., Inc.*, the court held finding the defendant, a manufacturer of generic Phenytoin, liable for "replicating, as required, the FDA-approved warnings used by Pfizer for Dilantin simply because a third party or the Federal Government might bring about conditions that would enable Mylan to comply with both state and federal law would eviscerate the supremacy clause." No. 6:11-cv-35, 2011 WL 170143, at *5 (S.D. Ga. Jan. 19, 2012) (Edenfield, J.). *See also Lyman v. Pfizer, Inc.*, No. 2:09-cv-262,

2012 WL 368675, at *5 (D.Vt Feb. 3, 2012) (Sessions, J.) (stating defendant was not only permitted, but required to update generic drugs labeling to reflect changes to the RLD labeling that were approved by the FDA).

To the extent Plaintiffs allege liability on the basis of a failure to warn, whether through a medication guide or labeling, Plaintiffs' causes of action are preempted by federal law.

b. Bioequivalence

Defendants' argument is twofold: (1) Plaintiffs allege Defendants failed to test for bioequivalence, but they do not allege the generic Phenytoin was not actually bioequivalent; and (2) Plaintiffs do not articulate how the alleged failure to test for bioequivalence contributed to their injuries. Defs.' Mem. in Supp. of Mot. to Dismiss, at 20–22. Defendants contend Plaintiffs' bioequivalence claims fail to state a plausible claim under Federal Rules of Civil Procedure 8(a)(2) and 12(b)(6).

Plaintiff offers no argument in response. Rather, Plaintiff asserts "the vitality of the bioequivalence . . . [argument is] dependent on evidence that has not been finally secured by the [Plaintiffs]. Thus, in the context of the present proceeding, [Plaintiffs] agree with [Defendants'] assertion that the gravamen of the [Amended Complaint] is the [Defendants'] alleged failure to warn about certain risks associated with [Phenytoin]." Pls.' Mem. in Opp'n to Mot. to Dismiss, at 6–7. Plaintiffs state they "do not raise the divergence on bioavailability as a case-specific source of injury." *Id.*, at 6 n.18. Because Plaintiffs raise no claim concerning bioavailability, this Court assumes they intended to refer to bioequivalence. Nonetheless, Plaintiffs have not opposed Defendants' arguments and have indicated they do not allege injuries resulting from the claimed lack of bioequivalence. The Court therefore has the discretion to deem Plaintiffs' claims abandoned to the extent they relate to bioequivalence. *Metlife Investors USA Ins. Co. v.*

Zeidman, 734 F. Supp. 2d 304, 313–14 (E.D.N.Y. 2010) (Spatt, J.); *Lipton v. Cnty. of Orange, NY*, 315 F. Supp. 2d 434, 446 (S.D.N.Y. 2004) (Connor, J.).

Furthermore, Plaintiffs' bioequivalence claims do not meet the pleading standard of Rule 8(a). A complaint "attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, [but] a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). A plaintiff must state a claim that is not merely conceivable, but plausible on its face. *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Facial plausibility is not a probability standard, but "asks for more than a sheer possibility that the defendant" has acted in the manner alleged. *Id.*

Plaintiffs fail to plead sufficient facts to state a claim concerning bioequivalence that is plausible on its face. The basis upon which Plaintiffs' bioequivalence claims rest is an alleged change in the process used to manufacture Dilantin undertaken by its manufacturer after Defendants' Phenytoin had been approved by the FDA. However, bioequivalence is not an inquiry into manufacturing processes. Rather, bioequivalence means the

> (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
> (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug

> concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355 (j)(8)(i) & (ii); *see also* 21 C.F.R. § 320.1 (Bioequivalence means the "absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."); *c.f.* 21 C.F.R. § 314.94 (a)(9). Plaintiffs do not plead facts that would permit this Court to infer the alleged change to Dilantin's manufacturing process either led to a significant difference between the rate and extent of absorption of Dilantin and generic Phenytoin, or that such difference caused Plaintiffs' injuries. Plaintiffs' conclusory claim that Defendants failed to test for bioequivalence is no different, particularly in light of their curious comment that bioequivalence is raised only "as a factor that disqualifies [Defendants] from claiming they are entitled to rely on" impossibility preemption. Pls.' Mem. in Opp'n to Mot. to Dismiss, 6 n.8. Indeed, that Plaintiffs concede they do not possess facts to support their bioequivalence claim furthers the conclusion that their claim is merely speculative, and nothing in the prolix and circuitous Amended Complaint leads this Court to believe discovery will lead to relevant evidence. *Twombly*, 550 U.S. at 556. Rule 8 is exceptionally permissive, but Plaintiffs cannot simply throw unfounded allegations at Defendants and hope that some will stick. The sheer possibility that a change in the process used to manufacture Dilantin caused a failure in the bioequivalence of Defendants' Phenytoin is insufficient to state a claim. *Iqbal*, 556 U.S. at 678. Therefore, Plaintiffs' claims are dismissed to the extent they concern bioequivalence.

c. <u>The Court must dismiss the Amended Complaint in its entirety</u>

Plaintiffs plead seven New York state law claims on the dual theories that Defendants failed to adequately warn of the risks of SCAR events, and failed to maintain bioequivalence between the generic drugs they produced and Dilantin. Plaintiffs' claims are preempted to the extent they allege a failure to warn. Plaintiffs have abandoned their claims to the extent they concern bioequivalence. Even if they had not, Plaintiffs fail to state a plausible claim concerning bioequivalence.

i. Strict Product Liability

Plaintiffs' first claim alleges strict product liability. Am. Compl., ¶¶ 176–93. The strict liability claim is broken into two parts. The first part alleges "the [Phenytoin] product label was inadequate in that it was not revised in a timely manner to reflect additional, new safety information that was contained in the product label for Dilantin" and because "it was not revised in a timely manner to include a 'Medication Guide' . . . even though a 'Medication Guide' was distributed with the brand product, Dilantin." *Id.* at ¶¶ 180–81. Plaintiffs allege Dilantin's 2009 labeling updates were implemented under the CBE process and therefore not approved at the time of their implementation. *Id.* at ¶¶ 128–35; Pls.' Mem. in Opp'n to Mot. to Dismiss, at 8, 13–18. To comply with its state law duty to warn, Defendants would have to violate federal law. Therefore, the first part of Plaintiffs' strict liability claim is therefore dismissed as preempted.

The second part of Plaintiffs' strict liability claim alleges the Phenytoin manufactured by Defendants was defective because it was not "shown to be bioequivalent to, and therefore identical to," Dilantin. Am. Compl., ¶ 189. Plaintiffs have not stated a plausible cause of action concerning bioequivalence. *See* § III.b, *supra.* Plaintiffs plead no facts that would enable this Court to reasonably infer Defendants are liable. Rather, Plaintiffs' claim is, in essence, a

"formulaic recitation of the elements of [the] cause of action." *Twombly*, 550 U.S. at 555. Plaintiffs' strict liability claim is dismissed in its entirety.

ii. Negligence

Plaintiffs' second claim alleges Defendants were negligent for failing to update their Phenytoin labeling, failing to distribute a medication guide, and failing to ensure bioequivalence. Am. Compl., ¶¶ 194–201. Plaintiffs again plead no facts to support their allegations concerning bioequivalence. Accordingly, Plaintiffs' negligence claim is dismissed as preempted and for failing to state a plausible claim.

iii. Fraud

Plaintiffs' third claim alleges common law fraud. *Id.* at ¶¶ 202–09. Plaintiffs allege "Defendants' fraudulent misrepresentations intentionally concealed [their failure] to conduct the necessary and appropriate tests to assure the ongoing bioequivalence of their phenytoin products" after the manufacturer of Dilantin allegedly underwent a manufacturing change in 2007. *Id.* at ¶ 206(a). As an initial matter, Plaintiffs have alleged no specific misrepresentation or omission and their claims are therefore subject to dismissal under the heightened pleading standards of Rule 9(b). More importantly, for the reasons stated above, simply because Plaintiffs have alleged a manufacturing change for Dilantin does not render their bioequivalence claims viable. Nor does the sheer possibility that Plaintiffs failed to test for bioequivalence or that the Phenytoin Plaintiffs' consumed was not, in fact, bioequivalent satisfy the pleading requirements of Rule 8(a).

Plaintiffs also allege "Defendants' fraudulent misrepresentations intentionally concealed [their failure] to revise their product labels to reflect the labeling changes and to include the Medication Guide" implemented by the manufacturer of Dilantin in July 2009. *Id.* at ¶ 206(b).

Plaintiffs again fail to point to a single misrepresentation or omission. Regardless, Plaintiffs' claims concerning labeling are preempted under *Mensing*. Plaintiffs' fraud claim is dismissed as preempted and for failing to state a plausible claim.

iv. Breach of Implied Warranties

Plaintiffs' fourth claim alleges the Phenytoin they consumed was not safe, fit for its intended use, or of a merchantable quality, "as warranted by [Defendants], in that [the Phenytoin] failed to include the revised 2009 warning that had been implemented by the RLD[.] Further, the products in question failed to include the Medication Guide, thereby rendering them unmerchantable." Am. Compl., ¶ 213. However, federal law forbids Defendants from adopting Dilantin labeling that had not received FDA approval. Therefore, Plaintiffs' breach of implied warranties claim, in essence a failure to warn claim, is preempted under *Mensing*.

Plaintiffs also allege the Phenytoin was not safe or fit for its intended use because Defendants failed to comply with their federal duty of sameness with respect to bioequivalence. *Id.* at ¶ 214. Plaintiffs allege "when the manufacturing process for [Dilantin] was revised, [Defendants] were no longer capable of warranting that their generic phenytoin products were of merchantable quality and safe and fit for the use for which [Phenytoin] was intended." *Id.* Plaintiffs plead no factual support for their allegations, and neither allege any basis upon which this Court could infer a connection between an alleged manufacturing change and bioequivalence, nor allege that any such deficiency caused their injuries. Plaintiffs' allegations raise no more than a "sheer possibility" that Defendants' Phenytoin was unsafe, unfit for its ordinary use, or merchantable. *Iqbal*, 556 U.S. at 678. Plaintiffs' claim for breach of implied warranties is dismissed as preempted and for failing to state a plausible claim.

v. Negligence Per Se

Plaintiffs' fifth claim alleges negligence per se. Am. Compl., ¶¶ 215–18. Plaintiffs base their claim on alleged violations by the Defendants of federal and state food and drug laws. *Id.* at ¶ 217. Plaintiffs allege Defendants violated the law by failing to update their labeling for Phenytoin, and by failing to monitor and test for bioequivalence with the RLD. *Id.* Plaintiffs' bioequivalence allegations again contain no factual support, much less the bare minimum required by Rule 8(a). Plaintiffs' negligence per se claim is therefore dismissed as preempted and for failing to state a plausible claim.

vi. Punitive Damages and Wrongful Death

Plaintiffs' punitive damages and wrongful death claims must be dismissed. Neither claim supplies an independent basis of recovery. Am. Compl., ¶¶ 219–33. Furthermore, the claims upon which each depends are preempted under *Mensing*. Plaintiffs' claim for punitive damages simply rehashes their failure to warn theory. *Id.* at ¶¶ 219–27. Plaintiffs' wrongful death claim conclusorily states certain Plaintiffs died as a result of exposure to Phenytoin, and Defendants therefore are liable to the decedents' estates. *Id.* at ¶¶ 229–33. However, the New York Court of Appeals has clearly stated a wrongful death claim belongs to the decedent's distributes, not the estate of the decedent. *Cragg v. Allstate Indem. Corp.*, 17 N.Y.3d 118, 121 (2011). Moreover, a wrongful death action is intended to compensate the decedent's distributes for their pecuniary losses arising from a defendant's wrongful act. *Id.* Here, the only wrongful acts Plaintiffs allege that could provide a basis of liability against the Defendants are dismissed as preempted or for a failure to state a plausible claim.

CONCLUSION

Each New York state law claim Plaintiffs plead in this action depend on their allegations that Defendant failed to adequately warn of the risk of SCAR events, and failed to test for and maintain bioequivalence with the Dilantin. Plaintiffs' failure to warn claims are preempted by federal law. Plaintiffs have both abandoned their bioequivalence claims, and, also failed to state a cause of action premised upon their bioequivalence claims. Therefore, the Amended Complaint is dismissed in its entirety.

SO ORDERED

Dated: Brooklyn, New York
November 9, 2012

s/WFK

HON. WILLIAM F. KUNTZ, II
United States District Judge